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Drug-eluting balloon in 001 bifurcated lesions: 1 year clinical and 7-months angiographic outcomes

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Background: In the DES era, the best strategy to treat 001 bifurcated lesions remains unanswered. This is the first prospective registry assessing the efficacy and safety of second generation of drug-eluting balloon (DEB) (EurocorGm), (3.0µg/m2 balloon surface area), in patients with 001 bifurcated lesions placed in secondary branches
Methods: After 2.7 years, 51 patients with 001 bifurcated lesion and clinical evidence of myocardial ischemia related to the target lesion were prospectively included in this multicenter (8 centers) registry. After optimal dilatation, a PEB was inflated for a minimum of 45 seconds. Left main bifurcated lesions, severe calcification and cardiogenic shock, were the only exclusion criteria. In 2 eligible patients after regular balloon pre-dilatation the DEB could not be used and patients were excluded of the registry.
Results: Patients were 62±12 years old, 42% diabetic, 56% ACS as clinical presentation. The most frequent lesion treated was first diagonal (41%). Radial approach was done in most cases (84%). Pre-dilatation was done in all the cases, with cutting balloon in 59%. Angiographic success was 90% (by protocol in 10% of lesions a BMS was implanted because of significant acute recoil (3) or coronary dissection more that type B (2)). At 1 month (follow-up completed in all the patients) there was no adverse event (MACE). At a mean of 11.2 ± 2.2 months (12 months completed in 81% of patients) there was 14.2% cumulative non-hierarchical MACE (1 MI, 0 cardiac deaths, 7 TLR). There was no thrombosis or occlusion. In 4 selected centers at a mean of 7.2 ± 1.1 months, angiographic follow-up was completed in 31/36 (86%) patients; reference diameter was 2.2 ± 0.3 mm with a binary restenosis of (6) 19.3%.
Conclusions: We report the first registry assessing 001 bifurcated lesion placed in small vessels (2.2mm). This is a rare type of coronary lesion (inclusion period of 2.7 years) that was observed in a relative young and diabetic population. In this complex setting, second generation of PEB is a safe strategy, technically easier and it seems to be effective at mid-term follow up with a 14% MACE at 1 year.

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A Novel Drug-Coated Scoring Balloon for the Treatment of Coronary In-Stent Restenosis: One Year Results of the PATENT-C First-in-Human Trial

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Background: Scoring balloons are useful in the acute treatment of in-stent restenosis, fibro-calcific and bifurcation lesions but have not been shown to affect the restenosis rate as compared to conventional balloons. A novel paclitaxel-coated scoring balloon (SB) was developed to overcome these limitations. Prior studies in a coronary swine model demonstrated a marked reduction in restenosis using these SB and no evidence of local or systemic adverse effects.
Methods: SB were coated with paclitaxel admixed with a specific excipient. Patients at 5 sites (4 in Germany and one in Brazil) with bare metal stent in-stent restenosis (ISR) were randomized 1:1 to treatment with either a drug-coated or bare SB. Baseline and 6-month follow-up quantitative coronary angiography was performed by an independent blinded core lab and all patients were evaluated clinically at 30 days, 6 and 12 months. The primary endpoint was angiographic in-segment late lumen loss (LLL). Secondary endpoints included clinically driven target lesion revascularization (TLR), major adverse cardiovascular events (MACE), stent thrombosis (ST) and other clinical and angiographic variables. Patients will be followed clinically for 2 years.
Results: A total of 61 patients were randomized (28 uncoated and 33 coated SB); mean age 63.3 yrs, males 72%, and presence of diabetes 38%. At 6-month angiography, late lumen loss in-segment was 0.48±0.51 mm in the uncoated SB group versus 0.09±0.43 mm in the drug-coated SB group (p=0.002; ITT analysis). The rate of binary restenosis was 41% in the uncoated SB group versus 6.5% in the drug-coated SB group (p< 0.05). At one year, the MACE rate was 32% with the uncoated SB vs. 6.7% with the drug-coated SB (p< 0.05).
Conclusions: A novel paclitaxel-coated coronary SB has been developed and achieved successful results in a first-in-human randomized controlled trial [ClinicalTrials.gov Identifier: NCT01495533].

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Characterization of vascular response and pharmacokinetics after application of paclitaxel-coated angioplasty balloons in non-diseased swine coronary arteries

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Background: Drug-coated balloons (DCB) rapidly transfer antirestenotic drug along the arterial vessel wall without a metallic implant. DCBs, coated with a mixture of paclitaxel and an excipient (to modulate drug release), may have clinical application in treating coronary in -stent restenosis and in peripheral arterial stenoses. This study characterizes the in vivo elution of paclitaxel and vascular compatibility of the novel Agent™ Paclitaxel-coated PTCA balloon for coronary vasculature.
Methods: The Agent DCB TransPAX coating consists of 80% Paclitaxel/20% excipient (2ug/mm2 dose density [Boston Scientific Corporation, Natick MA], "test DCB"). Controls included a commercially available paclitaxel-coated balloon (3ug/mm2, Pantera Lux [Biotronik AG, Switzerland] "control DCB") and an uncoated balloon ("POBA"). Balloons were inflated distal to a marker stent (BMS) or a BMS was implanted prior balloon inflation in the same position. The level of paclitaxel was measured at time points through 28d and vascular response was analyzed 28d post implantation.
Results: The level of paclitaxel in the coronary arteries was equivalent between test DCB and control DCB (reaching 50% of initial levels between 7 and 14d). Vessel areas were similar and endothelialization of luminal surfaces was nearly complete in all groups by 28d. Neointimal area was similar between test DCB and POBA; both were statistically less than control DCB. Medial smooth muscle cell loss and inflammation were greatest in control DCB vessels compared to test DCB vessels followed by POBA. Similarly, mean fibrin score (intima/media) was highest in the control DCB, followed by test DCB vessels and then POBA vessels (See table).

Balloon Treatment	Test DCB	Control DCB	POBA	ANOVA P-value
EEL Area (mm^2)	2.87±1.29	3.05±1.08	2.59±0.79	0.58
IEL Area (mm^2)	1.68±0.94	1.84±0.80	1.65±0.56	0.81
Neointimal area (mm^2)	0.11±0.08	0.31±0.27	0.12±0.18	0.03
% Stenosis	7.38±5.20	16.91±13.08	8.92±12.70	0.09
Mean PGs/ Collagen Score (Media)	1.17±0.72	2.07±0.65	0.79±0.81	0.0007
Medial SMC Loss Score (Circumference)	1.13±0.74	1.94±0.60	0.63±0.83	0.0007
Mean Fibrin (Intima/ Media) Score	0.88±0.91	1.61±0.79	0.042±0.14	<0.0001
Mean Inflammation (Intima/Media) Score	0.71±0.66	1.19±0.39	0.33±0.89	0.003

Abbreviations: EEL=external elastic lamina, IEL=internal elastic lamina, PG=proteoglycan, SMC=smooth muscle cell
% Stenosis defined as [1-(lumen area/IEL area)]*100

Conclusions: These results show the Agent DCB results in equivalent tissue levels with less nominal drug than the control DCB and support the safety of the Agent DCB in porcine coronary arteries.

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Synergy of Drug Coated Balloons plus Second-generation Drug Eluting Stents versus Second-generation Drug Eluting Stents: A Propensity Matched Analysis

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Background: Limited data are available as to whether the combination of drug coated balloons (DCB) plus drug eluting stents (DES) would be more efficacious than DES in lesions or patients at high risk for restenosis. A combination of paclitaxel (present in coated balloons) and a limus drug may exert a synergistic effect in preventing target lesion revascularization (TLR).
Methods: Between 2009 and 2013, 68 patients (82 lesions) were treated with a combination of DCB and implantation of a second-generation DES. These were compared to 513 lesions treated with conventional second-generation DES in the same period. Primary endpoint was TLR at 1- and 2-years of follow-up.
Results: The DCB plus DES group had more in-stent restenosis (ISR); 42.3% vs. 9.5%, p < 0.001 and higher prevalence of diabetes mellitus (DM); 36.4% vs. 22.2%, p = 0.007 compared to the DES group. After propensity matching, there were no